STRATEGIC PLAN FOR THE SURVEILLANCE, EDUCATION & PREVENTION, AND CARE, TREATMENT, & SUPPORT OF HEPATITIS C IN HAWAII

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I. Acknowledgements

A strategic plan for hepatitis C became a reality due to the dedication of key partners from a variety of organizations in Hawaii. Appreciation goes to those who attended the three planning sessions to develop the ideas and recommendations that comprise the strategic plan.

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II. Strategic Planning Process: Developing a Strategic Plan

The State of Hawaii Department of Health (DOH), with the recommendation of the Centers of Disease Control and Prevention, has identified the need for a strategic plan for hepatitis C surveillance, education, prevention, care, treatment, and support. In developing the initial draft of the Strategic Plan, the Hawaii Department of Health formed a committee comprised of local public health officials, hepatitis C advocates, physicians and other health care providers, public health educators, university and medical research personnel, correctional health system representatives, military and veteran health service providers, pharmaceutical representatives, and other community stakeholders. During the committee meetings, recommendations were made about issues regarding hepatitis C in Hawaii.

Beginning in January 2003, three follow-up sessions with the strategic planning committee were conducted. At each session, participants were divided into three smaller planning groups: 1) Surveillance, 2) Education & Prevention, and 3) Care, Treatment, & Support to examine current hepatitis C activities within the state and develop specific components of the strategic plan. Determining key action steps and evaluation plans for each goal identified by the planning groups was the main purpose of the strategic planning committee.

The timeframe for the Strategic Plan is three years. The strategic plan will serve as a road map to guide a statewide response to hepatitis C. The strategic plan will guide the community, policy makers, and prevention and service organizations to assess needs, prioritize issues, and direct decision-making. The purpose of the strategic plan is to:

1. Document significant facts relating to the epidemic of hepatitis C in Hawaii.
2. Clearly identify a vision and mission statement for hepatitis C in Hawaii.
3. Define goals and objectives in surveillance, prevention and medical management of hepatitis C infection.
4. Outline guidelines for achieving recommended goals and implementing and evaluating specific actions.

II. Strategic Planning Process: Where are we now?

Fundamental questions used to guide the strategic planning process include:

1. What do we know about the spread of hepatitis C infection in Hawaii?
2. What do we know about the need for prevention and education services regarding hepatitis C in Hawaii?
3. What do we know about the need for medical management and support systems regarding hepatitis C in Hawaii?
4. What do we know about the need for services of people who are at-risk for hepatitis C infection or are already infected with hepatitis C, especially those who are not privately insured?
5. How well are we doing in providing these services and/or programs?
6. What kind of barriers do people experience when trying to access services for hepatitis C?
7. Are there unmet needs?

Surveillance

A critical component to prevent and control hepatitis C infection and hepatitis C related chronic liver disease is an accurate surveillance system. Hepatitis C became a reportable disease in Hawaii in October 1997. The infection is on the list of notifiable diseases to be reported by all health care providers and clinical laboratories to the Hawaii Department of Health (DOH). The DOH created a hepatitis C registry to track all positive test reports that come from physicians, laboratories and other health care facilities such as Tripler Army Medical Center, The Veteran's Administration, Correctional Facilities, Drug Addiction Services of Hawaii, and the Diamond Head Health Center STD Clinic.
A cumulative report of positive hepatitis C tests from 1998-2002 indicate the following:

Island	Number of Positive Hepatitis C Tests
Oahu	4,111
Big Island	424
Maui	350
Kauai	132
Molokai	6
Tripler Army Medical Center	651

Early calculations indicate that there could be as many as 16,000-21,000 people in Hawaii that are hepatitis C positive. This suggests that 10,000-15,000 people may not be aware they are infected.

Other surveillance projects conducted by the Department of Health include:

1. A survey distributed to 652 practicing physicians to determine management practices of hepatitis C. The article can be found in the Hawaii Medical Journal, volume 60, p. 148-154.
2. A case-control survey of hepatitis C patients to assess behavioral risk factors conducted in 2000 indicated that injection drug use, having unprotected sex with an injection drug user and receiving a blood transfusion were the primary risk factors.
3. A seroprevalence study from frozen sera of incarcerated individuals in 1991-1993 indicated a prevalence of 17%, in 1999 a prevalence of 35% and in 2000 a prevalence of 24%. Injection drug use was determined to be the most common behavioral risk factor.
4. A seroprevalence study from frozen sera of patients attending the STD clinic at the Diamond Head Health Center from 1993-1994 indicated a prevalence rate of 3.6%

<u>Education & Prevention</u>

Presently, pharmaceutical representatives organize the majority of continuing education programs for health care professionals regarding hepatitis C. The AIDS Education Project (AEP) has also been instrumental in providing program opportunities for health care professionals in the realm of blood-borne infections, including hepatitis C.

Current activities regarding hepatitis prevention within the DOH include:

1) Conducting a train-the-trainer workshop for DOH and community-based agency personnel who provide prevention counseling and other services to people at-risk for hepatitis C,
2) Training DOH HIV counselor/testers and STD Disease Investigation Specialists in hepatitis A and hepatitis B immunization administration for the delivery point of care services to clients at-risk,
3) Partnering with the state syringe exchange program to offer education, vaccinations, HIV counseling/testing and Hepatitis C testing to a group of their clients.

Other educational and prevention efforts have been conducted with community-based organizations and advocacy groups such as public service announcements and participating in community forums.

Future education and prevention efforts will include partnerships with substance abuse treatment, correctional, and mental health facilities.

Currently, testing for hepatitis C is not performed in the public setting. Individuals who want to be tested for hepatitis C are referred to their primary health care provider.

Care, Treatment & Support

Currently, medical management of hepatitis is primarily concentrated within the medical specialty of gastroenterology. The Liver Center, located within the St. Francis Medical System on the island of Oahu, is the primary source for receiving referrals for people with hepatitis C in Hawaii.

Insurance coverage and disability benefits are not well understood for people with hepatitis C. Future plans include development of a resource directory to coordinate with various systems to streamline the process of referral to related programs and services.

Currently, there is one active support group in Hawaii located on the island of Oahu. Assistance is being given to others on neighbor islands to develop support groups for their communities. Future directions include re-building the infrastructure to include support groups within medical management systems.

III. The Strategic Plan

Vision Statement

To provide a client-centered, culturally appropriate and collaborative approach that is accessible, equitable and respectable within a seamless statewide system promoting:

- Awareness and education about hepatitis C to a variety of audiences.
- Elimination of stigma surrounding people infected with hepatitis C.
- Removal of barriers for obtaining prevention and care services.
- Hope and sensitivity toward people living with hepatitis C.
- Integrative and coordinated services across the continuum.
- Interventions based on harm reduction principles.
- Gathering accurate data regarding the incidence and prevalence of hepatitis in Hawaii to assist in evaluating programs within high-risk populations.
- Implementation of recommended standards of care regarding diagnosis and care of hepatitis C.

To stop the spread of hepatitis C and minimize the progression of chronic liver disease in people infected with hepatitis C in urban and rural areas of Hawaii by implementing a surveillance system and coordinating access to comprehensive and integrative prevention, education, screening, care, treatment, and support services that are efficient, cost-effective and client-centered.

To partner with public and private resources to offer hepatitis C education to health care providers, populations at-risk, and the general public to increase knowledge and awareness of this chronic disease.

Goals/Objectives/Action Steps

A.Surveillance

Goal #1 : Increase reporting to the Department of Health (DOH) from health care providers regarding hepatitis C.

Objective #1: By June 2004, the DOH in collaboration with other agencies will establish linkages with health care providers to provide education on hepatitis reporting procedures.

Action Steps:

- The Hepatitis C Surveillance Coordinator within the Disease Investigation Branch (DIB) of the DOH in collaboration with the Hepatitis C Program Coordinator of the STD/AIDS Prevention Branch (SAPB), the Hawaii Medical Association (HMA), and the Hawaii Nurses Association (HNA) will develop a strategy to educate health care providers of the importance of accurately reporting positive hepatitis C lab tests to the DOH.
- Incorporate hepatitis C reporting information into newsletters or other appropriate venues to reach health care providers.
- Assist health care providers in assessing whether cases should be reported as acute or chronic hepatitis C infection.
- Assist health care providers in improving their understanding of interpretation of anti-HCV screening test results, when more specific testing should be performed and which tests should be considered for this purpose.

Evaluation:

- Increase in accurately submitted reporting data from health care providers to the DOH.

Goal # 2: Increase reliable state-specific data regarding the prevalence of hepatitis C in Hawaii to provide data-driven information to guide program implementation and evaluation.

Objective #2: By June 2005, the DOH will, through reliable surveillance methods, present the burden of hepatitis C infection in Hawaii.

Action Steps:

- The Hepatitis C Surveillance Coordinator of the DIB in collaboration with the Hepatitis C Program Coordinator of the STD/AIDS Prevention Branch (SAPB) and other state and national resources will:
  1. Investigate a sample of the population at-risk for hepatitis C to determine behaviors that facilitate transmission of the hepatitis C virus and the development of interventions to stop transmission of the virus.
  2. Link investigations of the at-risk population to follow-up information including education, counseling, prevention services (i.e. hepatitis A & B vaccinations) and referral to community and medical resources.

Evaluation:

- Hepatitis C prevalence data within population samples will be conducted and reported to agencies to guide education, prevention and care interventions.
- Report on the number of identified cases that have been linked with necessary services.

B. Education

Goal #1: To increase information about hepatitis C provided to public and private health providers who offer services to persons at-risk for hepatitis C or to those who have been diagnosed with hepatitis C.

Objective #1 : By June 2004, develop statewide partnerships to establish local capacity to provide public and private health care professionals with education on the epidemiology, prevention, diagnosis, and treatment of hepatitis C.

Action Steps:

- The Hepatitis C Program Coordinator of the STD/AIDS Prevention Branch (SAPB) will work with local agencies in advertising educational offerings regarding hepatitis C.
- The Hepatitis C Program Coordinator of the STD/AIDS Prevention Branch (SAPB) will work to connect local and national experts in hepatitis C with Hawaii public/private health care providers and other health care professionals statewide for continuing education presentations and seminars.
- The Hepatitis C Program Coordinator of the STD/AIDS Prevention Branch (SAPB) will work with the HMA/HNA to disseminate national guideline

updates for the prevention, diagnosis, and treatment of hepatitis C to health care providers.

Evaluation:

- Report total number of hepatitis C educational opportunities made available to health care providers and professionals
- Linkage established with HMA/HNA on delivering updates to health care providers regarding hepatitis C.

Goal #2: Increase accurate information distributed to at-risk populations regarding hepatitis C.

Objective #2: By June 2004, develop and/or distribute educational information that is appropriate for addressing the educational needs of clients within agencies that provide prevention services for at-risk populations (i.e. substance abuse programs, syringe exchange programs, HIV prevention programs).

Action Steps:

- The Hepatitis C Program Coordinator of the STD/AIDS Prevention Branch (SAPB) and other coordinators within state agencies will identify resources to increase the capacity of agencies to provide education to at-risk populations including at a minimum:
  1. Train-the-Trainer Workshops
  2. Local, state, and national resources that provide written, telephonic, or computer-based education on hepatitis C.
  3. Integration of hepatitis C education into curriculum for staff in HIV, substance abuse, and correctional facility programs.

Evaluation:

- Report number of train-the-trainer workshops conducted and participants who have performed five trainings to agency and/or community members.
- Establish an email or other database system to notify agency personnel of resources available to them and their clients regarding hepatitis C.
- Report on the number of integrated trainings conducted with staff in HIV, substance abuse, and correctional facility programs. Conduct evaluations after training sessions to identify recommendations in the

training. Follow-up with quality assurance practices to assist staff in implementing hepatitis C education into their practice.

Goal #3: Increase awareness and knowledge of hepatitis C in the general public.

Objective #3: By June 2005, plan, develop, implement, and evaluate a statewide education campaign for hepatitis C that is grounded in scientifically based information.

Action Steps:

- A work group comprised of public and private agencies and community members will partner with the Hepatitis C Program Coordinator of the STD/AIDS Prevention Branch (SAPB) to educate the public on hepatitis C.
- The work group will contract with a marketing specialist to assist in planning and implementing a public education campaign.
- Secure funding for an education campaign regarding hepatitis C.
- Partner with the local "211" hotline to provide them with accurate and up to date information regarding national and local hepatitis educational resources and services.

Evaluation:

- Process evaluation on the work group progression and course of action to plan the education campaign.
- Provision of funding for education campaign.
- Determine trends in hepatitis C testing and reporting before and after an educational campaign.
- Determine trends in knowledge from a sample of the population before and after an educational campaign.

C. Prevention

Goal #1: Increase prevention and counseling services for persons at-risk for hepatitis C.

Objective #1: By June 2004, provide technical assistance to agencies regarding integrating counseling and prevention activities for people behaviorally at-risk for hepatitis C. These agencies may include at a minimum:

1. HIV/AIDS/STD programs
2. Syringe Exchange Programs
3. Substance Abuse Treatment Programs
4. Correctional Health Programs
5. Mental Health Programs
6. Veteran's Administration Programs

Action Steps:

- The Hepatitis C Program Coordinator of the STD/AIDS Prevention Branch (SAPB) and the Hepatitis C Surveillance Coordinator within the Disease Investigation Branch (DIB) will work to link populations behaviorally at risk for hepatitis C with agencies that can provide them with counseling and other prevention services. Resources for these agencies will include:
    1. Staff training, follow-up and support to integrate the unique aspects of hepatitis C into their practices.
    2. Data providing information on the incidence and prevalence of hepatitis C.
    3. Administering/referring for the hepatitis A and hepatitis B vaccinations.
    4. Linkages between department of health and other agencies to provide harm reduction activities such as:
        a. Sterile practices when using injection drug equipment
        b. Developing capacity for structured tattoo services in high-risk settings (i.e. correctional facilities)
        c. Condom availability

Evaluation:

- Quarterly follow-up with state and partner agencies regarding the success/challenges of integrating hepatitis into counseling practices.
- Provide data on sample populations to provide information to guide program intervention efforts
- Track number of hepatitis A & hepatitis B vaccinations given by trained DOH personnel
- Process evaluation regarding developing linkages and capacity for prevention programs.

Goal #2: Provide hepatitis C testing in public health settings (i.e. clinic, outreach, and substance abuse treatment settings).

Objective #2: By June 2004, identify lab capacity to make hepatitis C testing in public health settings accessible to clients behaviorally at-risk.

Action Steps:

- The Hepatitis C Program Coordinator of the STD/AIDS Prevention Branch (SAPB) and the Hepatitis C Surveillance Coordinator within the Disease Investigation Branch (DIB) will collaborate with state laboratories to determine feasibility and costs for implementing hepatitis C testing in public health settings.
- Determine what tests are needed when screening clients in a public health setting.
- Determine specific protocols for testing clients in a public health setting.
- Determine other opportunities for testing at-risk individuals (i.e. Hepatitis C Home Access Kits in the outreach setting)

Evaluation:

- Report on costs associated with confidential and/or anonymous hepatitis C testing.
- Report on what tests to include with hepatitis C testing within public programs.
- Report on insurance coverage associated with hepatitis C testing.

D. Care, Treatment, & Support

Goal #1: Increase knowledge and awareness regarding care, support, treatment, and insurance coverage for people and families living with hepatitis C.

Objective #1: By June 2004, design and implement a survey to be distributed to service providers, who will provide information on prevention, counseling, testing, medical management, alternative therapies, support group, and insurance services for people with hepatitis C. This information will be included in a statewide resource directory.

Action Steps:

- The Hepatitis C Program Coordinator of the STD/AIDS Prevention Branch (SAPB) and the Hepatitis C Surveillance Coordinator within the Disease Investigation Branch (DIB) will work in collaboration with other personnel to create and distribute a survey to determine potential referral sources to be included in a statewide resource directory.
- Fund the implementation of the survey and the creation and distribution of the resource directory through CDC and/or other financial sources.
- Explore insurance and/or medical assistance resources to help people with payment for medical treatments for hepatitis C.

Evaluation:

- Process evaluation to determine the progression and course of action of developing a survey and distributing it to potential referral sources
- Number of responses received from potential sources to be included in the resource directory
- Feedback from users of the resource directory

Goal #2: Increase the number of support groups available in the state.

Objective #2: By June 2006, the four main island counties will have access to hepatitis C support groups for individuals and families.

Action Steps:

- The Hepatitis C Program Coordinator of the STD/AIDS Prevention Branch (SAPB) will collaborate with community advocacy groups to

provide national resources and technical assistance to organizations engaged in establishing hepatitis C support groups.
- Partner with substance abuse treatment centers, mental health centers, and health care providers to integrate support groups into existing infrastructures.

Evaluation:

- Report on the number of support groups statewide.
- Process evaluation on coordinating with substance abuse and mental health centers to integrate support groups into current programs/services.

Goal #3: Increase access to hepatitis C medical evaluation and treatment for all people who are confirmed positive for the hepatitis C virus (i.e. mono- and co-infected persons).

Objective #3: By June 2006, establish private/public partnerships to provide opportunities for treatment.

Action Steps:

- The Hepatitis C Program Coordinator of the STD/AIDS Prevention Branch (SAPB) will work with other personnel of the SAPB to explore possibilities and will work with national agencies to determine feasibility for providing hepatitis treatment through the Hawaii Drug Assistance Program (HDAP) formulary for co-infected persons.
- Physicians with expertise in hepatitis C will lead the health care community in establishing a client-centered medical management model of care regarding hepatitis C by providing mentorship and guidance in diagnosing and treating hepatitis C to primary health care providers.
- Develop linkages among health care providers who have expertise in treating co-infected persons. (i.e. people who have expertise in hepatitis C in combination with other blood-borne infections such as HIV or hepatitis B).
- Provide guidance on opportunities for clients to become involved in clinical trials as a potential option for receiving treatment for hepatitis C.

Evaluation:

- Process evaluation on discussions regarding adding hepatitis medications to HDAP formulary.
- Process evaluation regarding the development of a client-centered medical management approach to treating hepatitis C.
- Report on increasing enrollment regarding clinical trials that are occurring with treatment and hepatitis C.

APPENDICES

Appendix I: National Hepatitis C Issues and Guidelines

Hepatitis C virus (HCV) was discovered in 1988 as the primary etiologic agent of parenterally transmitted non-A, non-B hepatitis and was known as post transfusion hepatitis. In the United States, the prevalence of antibody to HCV (anti-HCV) in the general population is 1.8%, as measured by the Third National Health and Nutrition Examination Survey. This corresponds to 4 million Americans infected with HCV, four times the number of HIV infection. Globally it is estimated that 3% of the world's population has been infected with HCV. This means that more than 170 million people are infected worldwide and makes hepatitis C a major global public health problem.

HCV affects persons of all ages, and all racial and ethnic groups. The occurrence of new HCV infection is most common in individuals ages 30 – 49 and in males. African Americans have a higher prevalence than Whites. The prevalence increases until age 40 in Whites, and until age 50 in Blacks, suggesting there is a large reservoir of relatively young Americans who are at risk of developing chronic liver disease and of serving as a source of new infection to others.

Both acute and chronic infections of HCV often produce only mild and nonspecific symptoms, making it difficult to accurately date the onset of infection.

ACUTE HCV INFECTION

The incubation period for acute hepatitis C after exposure from transfusion or needle stick is about 6 to 7 weeks and may range from 2 weeks to 6 months. Only 30% to 40% of adults with acute HCV infection have mild symptoms and/or develop jaundice. However, before the onset of symptoms, virus replication can be detected in the serum as soon as one week after exposure. The markers of virus that appear in the serum are: 1) HCV RNA detectable within 1 to 3 weeks of exposure. 2) After several weeks the serum alanine aminotransferase (ALT) level rises, and shortly thereafter clinical symptoms appear.

The severity of the acute illness can be varied: 60% – 70% of patients have no apparent symptoms; 20% – 30% may be ill with jaundice; and 10% – 20% may have non-specific symptoms such as loss of appetite, malaise or abdominal pain.

The most characteristic feature of acute hepatitis C is a variable ALT pattern. Normalization of ALT may occur and might suggest full recovery, but it is frequently followed by ALT elevation without symptoms indicating a chronic disease.

CHRONIC HCV INFECTION

More than 85% of patients with acute HCV infection will develop chronic hepatitis and about 60% of these patients will further progress to active liver disease that may lead to other complications of the liver. Some patients with cirrhosis remain asymptomatic until they have major complications. The most severe complication of chronic hepatitis C is the development of cirrhosis of the liver, which may develop rapidly (within 1 – 2 years of exposure), or slowly (within 2 – 3 decades). Symptoms of end-stage liver disease include marked fatigue, muscle weakness and wasting, fluid retention, ascites, jaundice, and dark urine. Once end-stage liver disease has developed, only liver transplantation can restore the health of the patient. Thirty percent of all transplantation cases are for end-stage liver disease due to hepatitis C. This makes hepatitis C a leading cause for liver transplantation in the U.S. Chronic hepatitis C is also a major cause of liver cancer, which may occur in patients with long-standing cirrhosis of the liver. Hepatitis C is responsible for 8,000 to 10,000 deaths each year nationwide.

RISK FACTORS

HCV is primarily transmitted by the parenteral route. Transmission through transfusions of blood products (once a major source) has been virtually eliminated in the United States over the past decade due to screening practices of blood donors. Injection drug use (IDU) is now the major route of HCV transmission. The prevalence of HCV among IDU ranges from 60 – 90% and is four times more common than HIV infection. Other sources of transmission are high-risk sexual behaviors, perinatal transmission, and occupational exposure. Although HCV is not easily transmitted sexually, sexual transmission is estimated to account for about 10% to 15% of cases in the United States. The risk of transmission is increased by large numbers of sexual partners, failure to use condoms, and prior history of sexually transmitted diseases (STDs). HIV infection may also facilitate sexual transmission of HCV. The occurrence of transmission of HCV among household contacts is probably due to inadvertent exposure to blood or infectious body fluids. The risk of HCV transmission from infected mother to her newborn infant is approximately 5 – 6%. Breast-feeding is not associated with HCV transmission. Health care workers are at risk for acquiring HCV infections primarily as a result of percutaneous exposures to

blood. The risk of infection after an accidental needle stick contaminated with HCV infected blood averages 2%.

Although the annual number of persons newly infected with HCV is declining, the number of persons who discover they are infected with the hepatitis C virus is expected to triple in the next 10 to 20 years.

SCREENING

Due to the nature of the disease, most people with hepatitis C do not know that they are infected, and most people have not been screened. It is important to obtain a history of high-risk exposures associated with HCV in the primary care or public health setting. Such histories can be used to identify persons who should be offered screening for HCV infection.

Identifying HCV infected persons through screening will provide opportunities for:

- Evaluating patients for chronic liver disease and possible treatment before irreversible damage has occurred.
- Counseling to avoid potential liver toxins such as alcohol that may increase the severity of the disease.
- Counseling on how to reduce the risk of transmission of the disease to others.
- Counseling on changing the risk behaviors and avoid contracting other diseases.
- Referral for substance abuse treatment.

Screening is recommended for persons with known high prevalence for HCV-infection including:

- Recipients of blood transfusions or solid organ transplants prior to 1992.
- Recipients of clotting factor concentrates prior to 1987.
- Injection drug users—even once, long ago.
- Long-term hemodialysis patients.
- Unexplained liver disease or abnormal liver tests.
- Children > 12 months old born to HCV infected women.
- Health care workers after accidental needle sticks, sharp, or mucosal exposures to HCV infected blood.

DIAGNOSIS

Several tests are available for the diagnosis of HCV infection. (See the Figure on page 25 for the updated guidelines on hepatitis C testing and reporting).

Enzyme Immunoassay (EIA)

EIA detects antibodies to HCV (anti-HCV) and is the initial test for the diagnosis of hepatitis C. EIA does not distinguish between acute, chronic, or resolved (past) infections. EIA specimens with a reactive result are retested in duplicate. If the results of either duplicate test are reactive, the specimen is defined as repeatedly reactive and is interpreted as screening-test-positive. Having antibodies to the hepatitis C virus does not confirm current infection. Only a PCR test for hepatitis C virus can confirm current infection. Positive EIA results occur in 50% of the patients infected with HCV within 9 weeks of exposure, in 80% of the patients within 15 weeks of exposure, and in > 97% of the patients within 6 months of exposure.

Supplemental Test, Recombinant Immunoblot Assay (RIBA)

The RIBA, a supplemental anti-HCV test with high specificity, is performed on screening-test-positive samples and provides results that are interpreted as positive, negative, or indeterminate. A confirmed anti-HCV positive result indicates the need for counseling and medical evaluation for HCV infection, including additional testing for the presence of virus and liver disease. A negative RIBA result is interpreted as anti-HCV-negative and indicates a false-positive screening test result. An indeterminate RIBA result indicates that the anti-HCV result cannot be determined. Another sample should be collected for repeat anti-HCV testing at least one month later.

Supplemental Test, Nucleic Acid Test (NAT)

NAT's that detect HCV RNA can also be used as supplemental test for anti-HCV. They are commonly used in clinical practice for diagnosis of acute and chronic HCV infection and for evaluating and managing patients with chronic hepatitis C.

1. HCV RNA Qualitative test

The HCV RNA Qualitative test will identify the HCV RNA using Reverse Transcriptase Polymerase Chain Reaction (RT-PCR). The presence of circulating HCV RNA indicates an active HCV infection because copies of the virus are detected in the blood (a condition called viremia). This test can detect the virus as early as 1–2 weeks after exposure. A single positive assay for HCV RNA by PCR will confirm HCV infection; however, a single negative assay does not confirm that the patient is not viremic or has recovered from hepatitis C. Fluctuating HCV RNA levels in the blood can be due to the irregular course of the infection. Therefore, follow up ALT testing and repeating the HCV RNA may be needed in the future.

2. HCV RNA Quantitative test

The HCV RNA Quantitative test is used to determine the viral titer by quantitative PCR or branched DNA amplification assays. This test is less sensitive than qualitative RT PCR, but is useful for assessing the response to antiviral therapy.

Reflex Supplemental Testing Using Screening-Test-Positive Signal/Cut-Off Ratios (s/co ratios)

Analysis of early versions of anti-HCV EIA results from volunteer blood donors indicated that average repeatedly reactive s/co ratios could be used to predict supplemental test-positive results. Additional data from CDC were generated to determine if a specific s/co ratio could be identified that would predict a true antibody-positive result > 95% of the time, regardless of the anti-HCV prevalence or characteristics of the population being tested. The results indicated that for licensed EIA's, reporting anti-HCV screening-test-positive results as anti-HCV positive for samples with average s/co ratios > 3.8 would be highly predictive of the true anti-HCV status. Reflex supplemental testing before reporting the anti-HCV results could be limited to screening-test-positive samples with average s/co ratios < 3.8. Implementation of the option for more specific testing based on the s/co ratio of screening-test-positive results will provide more reliable results for physicians and their patients so that further counseling and clinical evaluation are limited to those confirmed to have been infected with HCV. Implementation of this option will also improve public health surveillance systems for monitoring the effect of HCV prevention and control activities.

Genotype test

The genotype test identifies HCV genotypes and subtypes. There are 6 genotypes and >90 subtypes of HCV known. In the U.S., 70% of hepatitis C infection is caused by genotypes 1a or 1b. Knowing the genotype of HCV can determine the response to treatment. For example, patients with genotype 2 and 3 are more likely to have a sustained treatment response to interferon alpha than those with genotypes 1a or 1b. Also, there is an association between genotypes and modes of transmission. For example, genotype 3 is much more prevalent in IDUs.

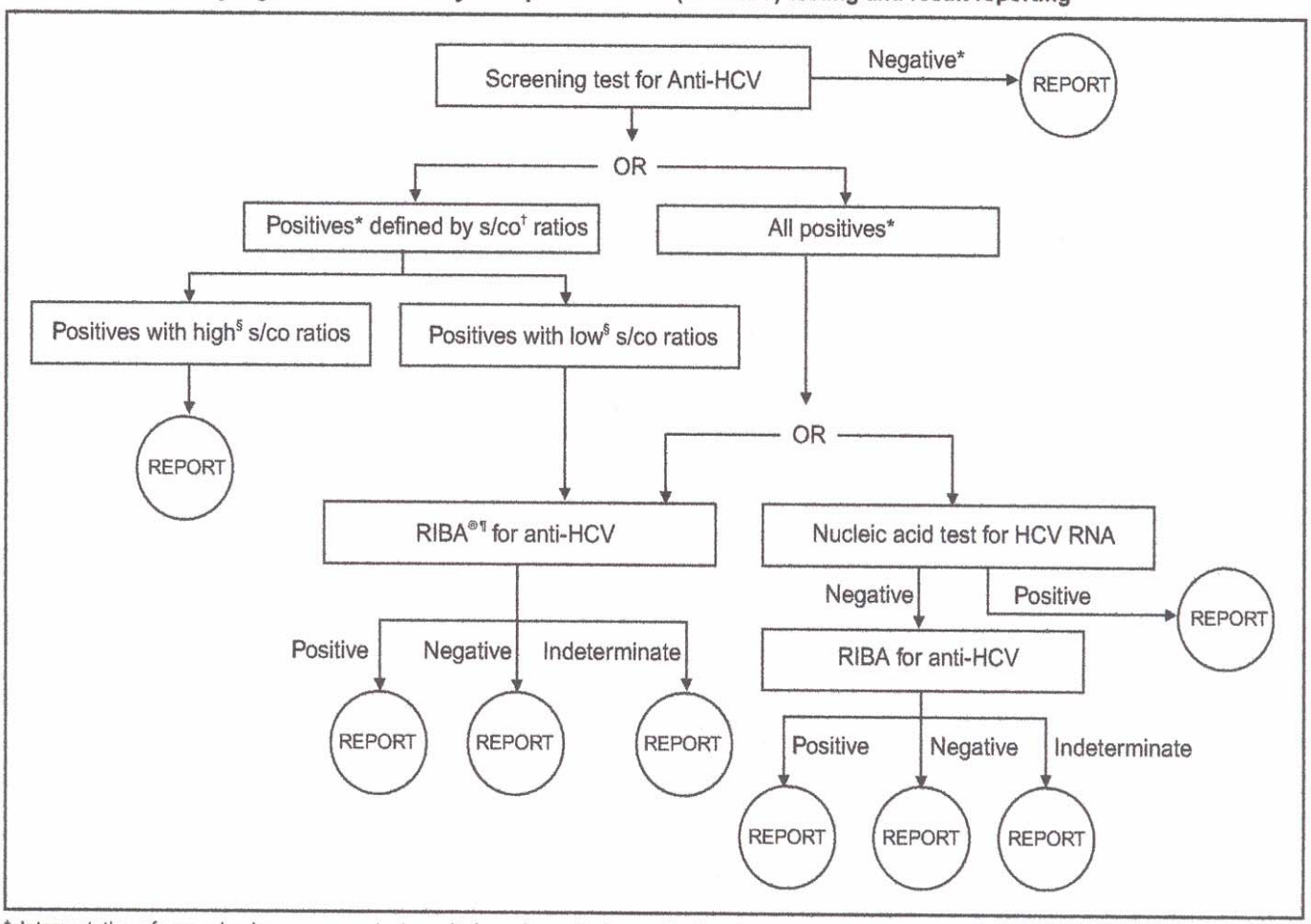
Serum ALT levels

Serum ALT levels can be used for assessing disease activity. Repeated elevations of ALT levels suggest ongoing liver disease. Normalization of elevated ALT levels during antiviral treatment is an important indicator of disease response. Therefore, serial tests of ALT levels can be used for monitoring patients with liver disease.

Liver Biopsy

Liver biopsy is the best method for assessing patients with chronic hepatitis. A biopsy can determine the severity of the liver disease and the degree of fibrosis. A liver biopsy is recommended to exclude other forms of liver diseases, such as concurrent alcoholic liver disease, medication induced liver injury, and iron overload.

FIGURE 4. Laboratory algorithm for antibody to hepatitis C virus (anti-HCV) testing and result reporting



* Interpretation of screening immunoassay test results based on criteria provided by the manufacturer.
† Signal-to-cut–off.
§ Screening-test–positive results are classified as having high s/co ratios if their ratios are at or above a predetermined value that predicts a supplemental-test–positive result ≥95% of the time among all populations tested; screening-test–positive results are classified as having low s/co ratios if their ratios are below this value.
¶ Recombinant immunoblot assay.

TREATMENT

At present, there is no vaccine against hepatitis C available, and no medication has been approved for post-exposure prophylaxis, therefore, diagnosis, treatment, and case management are the alternatives available.

The goals of hepatitis C treatment are to slow the disease by reducing the amount of virus in the body and slow damage to the liver caused by chronic hepatitis infections. The success of the treatment can be determined by studying the patient's therapeutic response by measuring the viral load at the End of-Treatment (ETR) and at 24-weeks after ETR. This indicates a sustained viral response (SVR).
Another goal is to decrease the infection's activity which will improve liver histology, slow the progression of the disease, reduce risks of hepatocellular carcinoma, and improve the quality of life.

Recommended treatment for hepatitis C is rapidly changing in clinical practice. Currently there are three treatment regimens that have been approved by the Food and Drug Administration (FDA) for HCV infection.

All patients with chronic hepatitis C are potential candidates for specific treatments. Treatment is recommended for patients with chronic hepatitis C who are at greatest risk for progression to cirrhosis, as characterized by persistently elevated ALT levels, detectable HCV RNA, and a liver biopsy indicating portal or bridging fibrosis or a moderate degree of inflammation and necrosis.

Interferon monotherapy

Interferon is a protein that helps the body's immune system attack the infected liver cells, and protect the healthy liver cells from new infection. The standard alpha interferon is given subcutaneously three times weekly in a dose of 3 million units for 6 – 12 months. One year after the end of therapy, only 15 - 25% of hepatitis C patients have persistently normal ALT levels and the absence of

viremia. Alpha interferon has significant potential side effects, which include flu-like symptoms, fatigue, alopecia, bone marrow suppression, and neuropsychiatric effects such as apathy, cognitive changes, irritability, and depression.

Combination Therapy of
Interferon alpha-2b and Ribavirin

A combination therapy, Interferon alpha-2b and Ribavirin, are packaged together as Rebetron.® Ribavirin is an oral antiviral agent given in doses of 500 – 600 mg twice daily. Ribavirin can cause hemolytic anemia, and has teratogenic effects, requiring female patients to avoid pregnancy during therapy. Combination therapy with two agents yields higher rates (40%) of sustained response than monotherapy. It is also more expensive and is associated with more side effects; however, in most situations, it is preferable. At present, interferon monotherapy should be reserved for patients who have contraindications to the use of Ribavirin.

Pegylated (PEG) interferon therapy

Pegylated interferon is a long lasting interferon. The efficacy of PEG interferons is enhanced by the addition of Ribavirin to treatment regimens. The increase in the half-life of PEG-interferon leads to sustained serum levels allowing once-weekly dosing. Sustained virologic responds rates observed in studies with pegylated interferon plus ribavirin exceed 50 %. PEG interferon in combination with Ribavirin has become the new regimen of choice for treatment of hepatitis C.

Immune Globulin
The value of immune globulin (IG) for prevention of hepatitis C is unclear. Available data suggest that post-exposure prophylaxis with IG is not effective in preventing infections.

Appendix II: Hawaii Hepatitis C Issues

Hawaii is beginning the process of integrating viral hepatitis into the larger system of health care. This will include surveillance, prevention counseling and other programs, vaccination opportunities for hepatitis A & B, testing options, access to medical evaluation and referral, and case management.

Hawaii is experiencing many of the same issues that are present in the national picture of hepatitis C infection. Among the key issues are: *(These issues are in no particular order)*

1) High prevalence of hepatitis C among people who use injection drugs.
2) High prevalence of viral hepatitis within the prison population.
3) Co-infection with HIV/HCV.
4) Insurance coverage for cost of testing and treatment for hepatitis C and coverage of preventive services, such as vaccinations for hepatitis A & hepatitis B.
5) Education of public and private health system providers in viral hepatitis and its management.
6) Improving the surveillance and reporting of hepatitis C.

High prevalence of hepatitis C among people who use injection drugs

Because both hepatitis B and hepatitis C are transmitted through exposure to infected blood and body fluids, people who use injection drugs are at increased risk for acquiring and transmitting these blood-borne viruses. It is estimated that 60% of new cases of hepatitis C in 2000 occurred among people who use intravenous drugs and that 50-80% of injection drug users become infected with hepatitis C within 5 years of beginning injection use.

In Hawaii, the exact percentage of hepatitis C among injection drug users is not currently known. A project is currently being conducted to estimate the number of people with hepatitis C who utilize methadone treatment facilities. Specific issues to address around hepatitis C in this population include education, prevention (vaccination, substance abuse treatment, syringe exchange program) and treatment and testing options.

High prevalence of viral hepatitis within the prison population

It is estimated through studies of prison populations in several states and examining national figures that 15-30% of inmates across the country may be infected with the hepatitis C virus.

In Hawaii, a seroprevalence study of hepatitis C markers performed on frozen sera of incarcerated individuals across the state showed an estimated prevalence of 17%, with people who use injection drugs at greatest risk. Specific areas to address around hepatitis C in the incarcerated population include collaborating with federal guidelines to develop policies for prevention counseling, screening, immunization, medical evaluation and management, and continuing care after the inmate's release.

Co-infection with HIV/HCV

With improved medical therapies, people with HIV (Human Immunodeficiency Virus) are living longer. If people living with HIV are also infected with HCV (Hepatitis C Virus), complications from HCV have more time to develop. Studies have shown that HIV infection in a person who is also infected with HCV results in higher levels of HCV in the blood and more rapid progression to HCV-related liver disease.

Nationally, the majority of HIV-HCV co-infected people are injection drug users. In Hawaii, there is a low percentage of HIV infection among injection drug users, due in large part to the statewide syringe exchange program. However, several AIDS Service Organizations across the state provide services to people who are co-infected and guidance of how to integrate viral hepatitis into existing prevention and case management programs is necessary.

Insurance coverage for cost of testing and treatment for hepatitis C and coverage of preventive services, such as vaccinations for hepatitis A & hepatitis B

The Centers for Disease Control and Prevention (CDC) estimates that expenditures for hepatitis C in the United States are over $600 million dollars annually. Individuals can spend up to $20,000 annually in health care costs to

treat and manage hepatitis C. This figure does not include work-loss costs and other indirect costs associated with managing this chronic condition.

In Hawaii, coverage of treatment for hepatitis C and coverage of preventive services varies depending on the health plan and geographic location. Guidance and planning is needed to determine the best options for providing these services to high-risk populations within the public and private health care system.

Education of public and private health system providers in viral hepatitis and its management

The need to educate and train health care professionals to improve the understanding of viral hepatitis risk factors, prevention, and care management is part of the CDC's national prevention strategy and the need has been expressed in Hawaii as the awareness increases with this chronic disease.

Improving the surveillance and reporting of hepatitis C

Hepatitis C became a reportable disease in Hawaii during October of 1997. Health care providers are required to report all acute cases of hepatitis C and clinical laboratories must report patients testing positive for hepatitis C to the State Department of Health. Prior to 1997, a total of 1,053 hepatitis C cases were reported to the Department Of Health. By 2001, more than 5,000 cases had been reported. Applying the national prevalence rate of 1.8%, this number is thought to be an under-representation of approximately 20,000 people who could be infected with hepatitis C. Increasing the reporting of hepatitis C cases in Hawaii will assist in monitoring trends in new infections, evaluating testing and counseling efforts, and identifying missed opportunities for hepatitis C prevention. Current database information does not contain patient-specific information concerning behavioral risk factors for infection or information on medical referral and follow-up.

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RESOURCE LINKS

Centers for Disease Control and Prevention (CDC)
Hepatitis Branch, Mailstop G37
1600 Clifton Road N.E.
Atlanta, GA 30333
404-639-3311
CDC Hepatitis Hotline: 1-888-443-7232
CDC Public Inquiries: 1-800-311-3435
Website: http://www.cdc.gov/ncidod/diseases/hepatitis/
Email: dvd1hep@cdc.gov

The National Institute of Health (NIH)
U.S. Department of Health and Human Services
Public Health Service
Office of Medical Applications of Research
Federal Building, Room 618
7550 Wisconsin Avenue MSC 9120
Bethesda, MD 20892-9120
301-496-1776
Website: http://www.hepcfoundation.org/InfoCent.html

Hepatitis C Global Foundation
1404 Madison avenue
Redwood City, CA 94061
650-369-0330
Website: www.hepcglobal.org

Hepatitis Foundation International (HFI)
30 Sunrise Terrace
Cedar Grove, NJ 07009-1423
1-800-891-0707
Website: www.hepfi.org
Email: HFI@intac.com

American Liver Foundation (ALF)

75 Maiden Lane, Suite 603
New York, NY 10038-4810
1-800-GO-LIVER
1-888-4-HEP-ABC
1-888-4-HEP-USA
Website: www.liverfoundation.org
Email: www.webmail@liverfoundation.org

The Hepatitis C Connection
1177 Grant Street, Suite 200
Denver CO 80203
303-860-0800
HepC Hotline: 1-800-522-HEPC
Website: www.hepc-connection.org
Email: info@hepc-connection.org

Hepatitis C Awareness Project
P.O. Box 41803
Eugene, OR 97404
541-607-5725
Email: hepcaware@aol.com

Hepatitis Education Project
4603 Aurora Avenue North
Seattle, WA 98103-6513
1-800-218-6932
206-732-0311
Website: www.scn.org/health/hepatitis/index.htm
Email: hep@scn.org

Hepatitis C Support Project
P.O. Box 427037
San Francisco, CA 94142
415-978-2400
Website: www.hcvadvocate.org
Email: sfhepcat@pacbell.nett

National Hepatitis C Advocacy Council (NHCAC)
Website: www.hepcnetwork.org

Veterans Aimed Towards Awareness
111 West Main Street
Middletown, DE 19709
302-633-5357
Website: www.veteranshepaware.com

Email: bakfield@aol.com

U.S. Department of Health and Human Services
Division of Transplantation
5600 Fisher Lane, Room 481
Rockville, MD 20857
301-443-7577
Website: www.hrsa.gov/osp/dot or www.organdonor.gov

Hepatitis Central
Website: http://hepatiti-central.com/vikki.html

A Hepatitis Resource
Website: http://home.texoma.net/~moreland/

Hepatitis Health Care Information Resource
Website: http://www.hsl.mcmaster.ca/tomflem/hepat.html

National Digestive Disease Information Clearinghouse
Website: http://www.niddk.nih.gov

HIV and Hepatitis
Website: http://www.hivandhepatitis.com

National Library of Medicine/Medline Plus/Information on Hepatitis C
Website: http://www.nlm.nih.gov/medlineplus/hepatitisc.html

PHARMACEUTICAL RESOURCES

Schering-Plough
1-800-222-7579
Website: www.schering-plough.com
Schering's Commitment to Care Program: 1-800-521-7157
Offers help in finding coverage, cost-sharing, and providing drugs to indigent people.

Roche Pharmaceutical
1-800-526-0625
Website: www.rocheusa.com
Roche's ONCOLINE Reimbursement Assistant Program: 1-800-443-6676

HEALTH-CARE PLAN RESOURCES

Quality Inter-Agency Coordination Task Force
Assist consumers with the process of choosing a suitable health plan
Website: www.healthfinder.gov/smarchoices/qualitycare/default.htm

National Committee for Quality Assurance
For help in evaluating health insurance plan
1-800-839-6487
Website: www.ncqa.org

National Association of Insurance Commissioners
For listing of state insurance department
816-842-3600
Website: www.naic.org